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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/419,262	10/12/1999	LARS E. FRENCH	11141/003001	9978

7590 10/09/2002

J PETER FASSE
FISH & RICHARDSON P C
225 FRANKLIN STREET
BOSTON, MA 021102804

EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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ART UNIT	PAPER NUMBER
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DATE MAILED: 11/29/2001

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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/4/01.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) 3 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1,2,4-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-20 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

* U.S. GPO: 1996-409-290-40029

Part III: Detailed Office Action

Notice: Effective June 18, 2000, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Lorraine Spector, in Group Art Unit **1647**.

Claims 1, 2 and 4-20 remain under consideration. All previous rejections of claims under 35 U.S.C. §102 and §103 are withdrawn in view of applicants arguments.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lynch et al., U.S. Patent Number 5,830,469.

Lynch et al. teach FAS antagonists and uses thereof, including methods of inhibiting Fas-ligand mediated apoptosis using anti-FAS antibodies, see for example claim 1. Treatment of HIV/AIDS is taught at column 12, and claimed in claim 19. Humanized monoclonals are taught, see claims 6, 9 and 12, as well as column 12, lines 45-49 for example. Lynch et al. also teach that determination of dosage is routine, see col. 12 lines 58-67. At column 14, Lynch et al. teach that treatment with anti-FAS antibodies is functionally equivalent to treatment with anti-FAS Ligand antibodies, see lines 13-24.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al., U.S. Patent Number 5,830,469.

The teachings of Lynch et al. are discussed above. The reference differs from the claims only in that the specific route of administration (intravenous) and dosage amounts are not disclosed. However, as discussed above, Lynch et al. teach that determination of dosage is routine in the art. Accordingly, in the absence of any unexpected results, the particularly recited dosages are considered to be *prima facie* obvious over the disclosure of Lynch et al. Further, one of skill in the art would have been motivated to use an intravenous dosage as such is notoriously old and well known in the art as being a preferred mode of administration of various pharmaceuticals, including antibodies, and would have been aware of the advantages (sustained dosage levels and ease of administration) of intravenous administration. Accordingly, the invention if *prima facie* obvious over the prior art.

Claims 1, 2 and 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hattori et al., Blood 91:4051-4055, in view of Lynch et al., U.S. Patent Number 5,830,469.

As set forth in the previous Office Action, Hattori et al. teach a method of treating a subject having GVHD, using a composition comprising antibodies to Fas ligand (see page 4051, col. 2 and page 4052, col.2). Hattori also teaches that the composition is administered at a dose of 0.1 g/kg over a period of 7 days (see page 4051, col. 2 and page 4052, col. 2), as recited in claims 9, 11, 16

and 19. Hattori also teaches the use of anti-Fas ligand antibodies in humans (see page 4054, col. 2, last paragraph), as recited in claim 15.

The claimed invention differs from the Hattori et al. disclosure in that it teaches administration of anti-Fas *ligand* antibodies, and does not teach or suggest administration of anti-Fas antibodies. Additionally, the claimed invention differs from the Hattori et al. disclosure by the recitation of the composition being administered as an intravenous immunoglobulin mixture as recited in claims 5 and 14, and wherein the immunoglobulin mixture is administered at a dose of at least 0.75 g/kg/day.

The teachings of Lynch et al. are discussed above.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute the antibodies of Lynch et al. in the method of Hattori et al. for the treatment of GVHD. One of skill in the art would have been motivated to do so, and would have expected success, in view of Lynch's teaching of the equivalence of anti-Fas Ligand and Anti-Fas antibodies for the blocking of signaling via FAS. With respect to particular dosages, the particularly recited dosages are considered to be *prima facie* obvious over the disclosures of Hattori et al., who teaches dosages consistent with claims 9, 11, 16, and 19, and Lynch et al., who teach that determination of dosage is routine in the art. Further, one of skill in the art would have been motivated to use an intravenous dosage as such is notoriously old and well known in the art as being a preferred mode of administration of various pharmaceuticals, including antibodies, and would have been aware of the advantages (sustained dosage levels and ease of administration) of intravenous administration. Accordingly, the invention if *prima facie* obvious over the prior art.

Advisory Information:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Spector via telephone number 703-746-5228. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Lorraine Spector, Ph.D.
Primary Examiner

LMS
09/419262.s1
11/27/01